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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/787,215 05/17/01 KIRCHHOLTES P D/98409 US

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EXAMINER

JIANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/787,215

Applicant(s)

KIRCHHOLTES ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This application is a 371 of PCT/EP99/07768.

This application claims the foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sas et al. (EP 389035 A1, PTO-1449 submitted March 15, 2001).

Sas et al. teaches highly pure (7α , 7α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one (tibolone) comprising (7α , 7α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount less than 0.5%, 0.25%, or 0.1% by weight. Sas et al. also teaches a dosage unit comprising a pharmaceutically suitable solid carrier and the highly pure (7α , 7α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an amount of less than 2.50 mg and (7α , 7α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount less than 0.5% by weight. See abstract and Examples 1-8. Thus, Sas et al. anticipates the claimed invention.

Claims 9-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Haan De et al. (WO 98/47517, PTO-1449 submitted March 15, 2001).

Haan De et al. teaches a dosage unit comprising a pharmaceutically suitable solid carrier and the highly pure (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an amount of less than 2.50 mg, 1.25 mg, or 0.625 mg and (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount less than 0.5% by weight. Sas et al. also teaches the self life periods of the instant claim. See abstract, page 1 lines 3-5 and 23-30, page 2 the last paragraph and Examples 1-4 and 6-11. Thus, Haan De et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al. (AJ, PTO-1449 submitted March 15, 2001) and Van Vliet et al. (AR, PTO-1449 submitted March 15, 2001).

Sas et al. teaches a process for preparing the high pure (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one comprising aging crystal of (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one (seed crystals) in the presence

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of water for one hour. Sas et al. also teaches the steps of the process herein such as pouring out the solution in water with small amount of pyridine which makes the solution slightly alkaline and washing the crystals with water and small amount of pyridine which makes the solution slightly alkaline. See Examples 1-4.

Vliet et al. teaches the last step of synthesis of (7 α , 7 α)-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one: reacting (7 α , 7 α)-3,3-dimethoxy-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an organic solvent with aqueous oxalic acid (a weak acidic aqueous solution). See page 112 the last line of the 2nd paragraph to the first line of the 1st paragraph.

The prior art does not expressly disclose that the step of the process herein for aging crystals lasts for at least 24 hours or 3-6 days.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to optimize the time period for aging crystals to at least 24 hours or 3-6 days.

One having ordinary skill in the art at the time the invention was made would have been motivated to optimize the time period for aging crystals to at least 24 hours or 3-6 days because the optimization of the time period for aging crystals to longer period of time in order to obtain more desirable crystals, e.g. highly pure or desired polymorphous forms, is considered well within the skill of artisan.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

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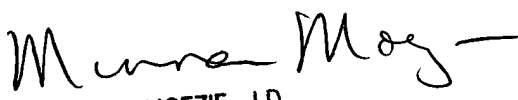
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
July 18, 2001


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